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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,385	08/15/2007	Marco Antonio Santini	4705-0121PUS1	2824
2292 7590 05/30/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER THOMAS, TIMOTHY P				
ART UNIT		PAPER NUMBER		
1614				
NOTIFICATION DATE		DELIVERY MODE		
05/30/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/582,385

Applicant(s)

SANTINI ET AL.

Examiner

TIMOTHY P. THOMAS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-33, 40, 41 and 45-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1, 2, 4-33, 40, 41 and 45-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF008)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 41, 48, drawn to a pharmaceutical composition.

Group II, claim(s) 49, drawn to a method for treating a neoplastic tumor.

Group III, claim(s) 28-33, 40, 45-46, and 47 (in part), drawn to a process for the preparation of sterile solutions of active pharmaceutical ingredients.

Group IV, claim(s) 1-2, 4-6, drawn to a process for the preparation of anhydrous active pharmaceutical ingredients comprising azeotropic distillation.

Group V, claim(s) 8-10, drawn to a process for the preparation of anhydrous active pharmaceutical ingredients comprising reaction in an anhydrous solvent and direct isolation in a pure and anhydrous form.

Group VI, claim(s) 11-16, drawn to a process for the preparation of anhydrous docetaxel comprising purification by chromatography.

Group VII, claim(s) 17-27, and 47 (in part), drawn to a process to effect the solubilization of docetaxel comprising inducing crystallization, isolation and drying of the crystals.

Note: claim 7 depends on a canceled claim; it is not clear what the subject matter of this claim is; upon amendment to clearly reflect the subject matter of one of the above groups, the claim may be rejoined with that group.

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2. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking the groups is some type of purification process of a taxane derivative or a composition containing anhydrous or hydrated taxane derivatives. Sharma et al. (US 2004/0116720 A1; 2004 Jun; priority date 2003 Apr) teaches a process for the preparation of paclitaxel trihydrate or docetaxel trihydrate comprising treating the taxane with a mixture of alkane and chlorinated alkane, dissolving the crude product in alkyl ketone, followed by slow addition of an alkane to increase chromatographic purity, dissolving this taxane in an aliphatic nitrile, adding purified water to precipitate taxane trihydrate, filtering and drying the product (abstract; claims). Since the prior art teaches the technical feature, the technical feature is not "special". Accordingly the groups are not so linked by the same or a corresponding special technical feature as to comprise a single general inventive concept.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

For any one of Groups I-VII elected applicant is required to elect:

(i) a single disclosed active ingredient, elected from compounds I, II or III (claims 2, 17, 31, 48);

and

If one of Groups III-VII is elected applicant must also elect:

(ii) a single disclosed solvent or mixture of solvents used in the process of the elected claim(s) 1, 8, 13, 17, or 28, elected from the solvent compound species recited in claims 5-7, 9-10, 15-16, 18, 21-22, 25, 28, 36, 40;

and

If Group III or VII is elected applicant must also elect:

(iii) a single disclosed stabilizing agent (claims 28, 40, 47) or mixture of stabilizing agents (claims 28, 40, 46, 47); elect each stabilizing agent compound specie present from the species antioxidant (claim 28) or a one of the acids recited in claim 40, 45 and 47.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

(i) all claims

(ii) claims 1-2, 4-33, 40, 45-47

(iii) claims 28-33, 40, 45-46, and 47

The following claim(s) are generic: claims 1, 28, 33, 40-41, 45-49 are generic for (i); claims 1-2, 4-6, 8-9, 11-14, 16-20, 23-31 are generic for (ii); claims 28-33, 40, 45-47 are generic for (iii).

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The technical feature linking the species is (i) a taxel derivative; (ii) a metastatic tumor; (iii) a solvent/solvent system. Each of these species has been taught by Sharma et al. (US 2004/0116720 A1; 2004 Jun; priority date 2003 Apr), as outlined above, with the additional reference to the teaching that paclitaxel and docetaxel are approved chemotherapeutic drugs for the treatment of metastatic cancers (paragraph 002). Since the prior art teaches the technical features linking the species, the technical features are not "special". The stabilizing agent species (iv) have different structures and therefore lack unity a priori. Therefore, the species do not comprise a special technical feature and the species are not so linked by the same or a corresponding special technical feature as to comprise a single general inventive concept.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

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requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

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are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY P. THOMAS whose telephone number is (571)272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614